

MAR 07 2007

PAGE 5/19 * RCVD AT 3/7/2007 3:51:25 PM [Eastern Standard Time] * SVR:USPTO-EFAXRF-1/4 * DNIS:2738300 * CSID:8123309049 * DURATION (mm-ss):05-20

PATENT

Serial No. 09/777,091

CLAIMS

BEST AVAILABLE COPY

- 1 1. (Currently amended) An implantable valve for a bodily passage of
- 2 tubular shape, comprising:
- 3 a self-expanding support frame configured for expansion to
- 4 conform to a wall of the bodily passage, said support frame having a
- 5 plurality of bends, said plurality of bends configured to provide outward
- 6 radial force for expansion of said self-expanding frame to anchor the
- 7 implantable valve to the wall of the bodily passage, said support frame
- 8 when expanded providing a plurality of side elements each defining a
- 9 path extending at least partially longitudinally along the wall and at least
- 10 partially circumferentially around the wall,
- 11 a plurality of leaflets, each leaflet thereof having a body extending
- 12 from a wall-engaging outer edge to an inner edge proximate a
- 13 corresponding inner edge of at least one other leaflet of the plurality of
- 14 leaflets,
- 15 the inner edges of said plurality of leaflets cooperable to define an
- 16 opening therebetween to permit fluid flow in a first direction along the
- 17 bodily passage, and further cooperable to engage each other sufficiently
- 18 to restrict fluid flow in a second direction opposing the first direction,
- 19 the outer edge of each one of the plurality of leaflets includes an
- 20 attachment extending along at least selected ones of the side elements such
- 21 that the outer edge is attached along one side element of said plurality of
- 22 side elements and thereby adapted to resiliently and sealingly engage
- 23 the wall of the bodily passage along in said path extending at least
- 24 partially longitudinally and at least partially circumferentially such that
- 25 the ,each leaflet extending extends along said bodily passage away from
- 26 the inner edges thereof in said second direction to form ,each of said
- 27 leaflets thereby forming a curved structure for trapping fluid against
- 28 between the leaflets and the inner wall of the bodily passage in response
- 29 to fluid flow in said second direction so as to cause said inner edges of

Serial No. 09/777,091

PATENT

30 said leaflets to engage one another sufficiently to restrict fluid flow in
31 said second direction.

1 2. (Previously presented) The implantable valve of claim 1, wherein at
2 least a portion of the body of the leaflet being flexible at least proximate
3 the inner edge thereof.

1 3. (Canceled)

1 4. (Previously presented) The implantable valve of claim 1 wherein the
2 outer edges of the plurality of leaflets include overhanging material, the
3 overhanging material extending beyond the frame to which the plurality
4 of leaflets are attached.

1 5. (Previously presented) The implantable valve of claim 1 wherein said
2 frame comprises wire to and around which the bodies of the leaflets are
3 secured.

1 6. (Previously presented) The implantable valve of claim 1 wherein the
2 plurality of leaflets includes two leaflets such that when the frame is
3 substantially flattened, it assumes a diamond shape with the inner edges
4 of the two leaflets defining a slit therebetween.

1 7. (Currently amended) The implantable valve of claim 1 3 wherein the
2 body and the frame of each leaflet comprises an integral, one-piece
3 member.

1 8. (Currently amended) The implantable valve of claim 7 4 wherein said
2 integral, one-piece member is molded into a generally flat shape.

Serial No. 09/777,091

PATENT

- 1 9. (Original) The implantable valve of claim 7 wherein said integral, one-
2 piece member is molded into a serpentine shape.

- 1 10. (Previously presented) The implantable valve of claim 1 wherein the
2 plurality of leaflets comprises an extracellular collagen matrix.

- 1 11. (Previously presented) The implantable valve of claim 1 wherein the
2 extracellular collagen matrix includes small intestinal submucosa.

- 1 12. (Currently amended) The implantable valve of claim 1 comprising a
2 pair of opposing ~~two~~ leaflets forming a bi-leaflet valve.

- 1 13. (Original) The implantable valve of claim 1 wherein the frame is
2 adapted to assume a plurality of configurations, the plurality of
3 configurations includes a generally flat configuration, whereby the frame
4 in the generally flat configuration is generally diamond-shaped.

- 1 14. (Canceled)

- 1 15. (Original) The implantable valve of claim 1 further including at least
2 one barb to anchor the implantable valve to the wall of the bodily
3 passage.

- 1 16. (Original) The implantable valve of Claim 15 wherein the at least one
2 barb is integral projection extending from the frame.

- 1 17 - 54 (Canceled)

- 1 55. (Currently amended) An implantable valve for a bodily passage of
2 tubular shape, comprising:

Serial No. 09/777,091

PATENT

3 a support frame configured for expansion to conform to a wall of
4 the bodily passage, said support frame when expanded providing a
5 plurality of side elements each defining a path extending at least partially
6 longitudinally along the wall and at least partially circumferentially
7 around the wall,

8 a plurality of leaflets comprising an extracellular collagen matrix
9 material, each leaflet thereof having a body extending from a wall-
10 engaging outer edge to an inner edge proximate a corresponding inner
11 edge of at least one other leaflet of the plurality of leaflets,

12 the inner edges of said plurality of leaflets cooperable to define an
13 opening therebetween to permit fluid flow in a first direction along the
14 bodily passage, and further cooperable to engage each other sufficiently
15 to restrict fluid flow in a second direction opposing the first direction,

16 the outer edge of each one of the plurality of leaflets attached
17 along one side element of said plurality of side elements and thereby
18 adapted to directly engage the wall of the bodily passage therearound
19 and provide ingrowth of adjacent native tissue into the extracellular
collagen matrix material.

1 56. (Previously presented) The implantable valve of claim 55 wherein the
2 collagen matrix material comprises submucosal tissue.

1 57. (Previously presented) The implantable valve of claim 55 wherein the
2 collagen matrix material comprises small intestinal submucosa.

1 58. (Previously presented) An implantable valve for a bodily passage of
2 tubular shape, comprising:

3 a frame that includes a plurality of legs, each of the legs
4 originating from a pair of bends located about a first end of the
5 implantable valve, and extending in an opposite direction therefrom,
6 each of the plurality of legs terminating at a second end of the

Serial No. 09/777,091

PATENT

7 implantable valve opposite the first end such that the plurality of legs
8 generally assume a serpentine configuration along the circumference of
9 a bodily passage when situated therein,
10 a plurality of leaflets, each leaflet comprising a covering that
11 includes one or more flexible materials, the leaflet including a body that
12 comprises a wall-engaging outer edge and an inner edge, the outer edge
13 at least partially attached to, and reinforced by one of the plurality of
14 legs, the outer edge and the associated leg adapted to sealingly engage
15 the inner wall of the bodily passage,
16 wherein the body of the leaflet extends inward from the wall of the
17 bodily passage and extending toward the first end of the implantable
18 valve where it terminates at the inner edge, the body and inner edge
19 traversing the lumen of the bodily passage when situated therein and
20 being configured such that the leaflet is cooperable with at least one
21 other leaflet to define an opening that permits positive flow of fluid
22 therethrough in a first direction, while the plurality of leaflets are further
23 adapted to trap between the leaflets and the inner wall of the bodily
24 passage fluid flowing in a second direction opposite the first direction
25 and seal against one another to restrict fluid flow in said second
26 direction; and
27 wherein the frame is adapted to assume a plurality of
28 configurations, a first configuration of the plurality of configurations
29 being a generally flat plane.

1 59. (Previously presented) An implantable valve for a bodily passage of
2 tubular shape, comprising:
3 a frame that includes a plurality of legs, each of the legs
4 originating from a pair of bends located about a first end of the
5 implantable valve, and extending in an opposite direction therefrom,
6 each of the plurality of legs terminating at a second end of the
7 implantable valve opposite the first end such that the plurality of legs

Serial No. 09/777,091

PATENT

8 generally assume a serpentine configuration along the circumference of
 9 a bodily passage when situated therein,
 10 a plurality of leaflets, each leaflet comprising a covering that
 11 includes one or more flexible materials, the leaflet including a body that
 12 comprises a wall-engaging outer edge and an inner edge, the outer edge
 13 at least partially attached to, and reinforced by one of the plurality of
 14 legs, the outer edge and the associated leg adapted to sealingly engage
 15 the inner wall of the bodily passage,
 16 wherein the body of the leaflet extends inward from the wall of the
 17 bodily passage and extending toward the first end of the implantable
 18 valve where it terminates at the inner edge, the body and inner edge
 19 traversing the lumen of the bodily passage when situated therein and
 20 being configured such that the leaflet is cooperable with at least one
 21 other leaflet to define an opening that permits positive flow of fluid
 22 therethrough in a first direction, while the plurality of leaflets are further
 23 adapted to trap between the leaflets and the inner wall of the bodily
 24 passage fluid flowing in a second direction opposite the first direction
 25 and seal against one another to restrict fluid flow in said second
 26 direction; and
 27 wherein the frame is adapted to assume a plurality of
 28 configurations, a first configuration of the plurality of configurations
 29 being a generally flat plane; and
 30 wherein the covering includes two leaflets such that when the
 31 frame in the generally flat configuration generally assumes a diamond
 32 shape with the inner edges of the two leaflets defining a slit
 33 therebetween.

1 60. (Currently amended) A bi-leaflet valve prosthesis for an implantation
 2 in a blood vessel, comprising:
 3 a support frame including a plurality of bends and interconnected
 4 sides, the support frame having a first configuration for intravascular

Serial No. 09/777,091

PATENT

5 delivery into the blood vessel and a second configuration for
6 implantation therein;
7 a pair of opposing ~~plurality of~~ leaflets, each leaflet having an inner
8 edge and an outer edge;
9 wherein the inner edges of the ~~opposing plurality of~~ leaflets are
10 cooperable with one another to permit blood flow in a first direction
11 within the vein, while restricting blood flow in a second direction
12 opposite the first direction; and
13 wherein the outer edge of each of the plurality of leaflets is
14 attached to at least one of the plurality of interconnected side elements
15 such that the plurality of outer edges engage the walls of the bodily
16 passage and collectively form a seal thereagainst along a pathway
17 defined by the plurality of interconnected side elements.

1 61. (Currently amended) The valve prosthesis of claim 55 wherein the
2 plurality of leaflets comprise a bioremodelable material.

1 62. (Previously presented) The valve prosthesis of claim 61 wherein the
2 plurality of leaflets comprise an extracellular collagen matrix.

1 63 (Previously presented) The valve prosthesis of claim 60, wherein the
2 leaflets form a curved structure for trapping fluid between the plurality
3 of leaflets and the inner wall of the blood vessel in response to fluid flow
4 in the second direction so as to restrict the flow passing through the
5 valve prosthesis in the second direction.

1 64. (Currently amended) The valve prosthesis of claims 60, wherein the
2 plurality of bends include at least a first bend and a second bend located
3 about the first end of the prosthesis, the first bend and the second bend
4 interconnecting two of the plurality of interconnected sides, each of with
5 the two interconnected sides extending a least partially longitudinally

Serial No. 09/777,091

PATENT

6 from the first bend and the second bend toward the second end of the
7 prosthesis; and wherein the inner edges of the plurality of leaflets each
8 include a first end and a second end, each of the first and second ends
9 being carried about at least one of the first bend and the second bend.

1 65. (Previously presented) The valve prosthesis of claim 64, wherein the
2 first bend and the second bend each carry one of the first end or the
3 second end of each of the plurality of leaflets.

1 66. (New) A bi-leaflet vascular valve prosthesis, comprising:
2 a support frame including a plurality of bends and interconnected
3 side elements, the support frame having a first configuration for
4 intravascular delivery and a second configuration for implantation in a
5 vascular vessel;

6 the plurality of bends including a first bend and a second bend,
7 wherein the first bend and the second bend are adapted to be positioned
8 opposite one another when the support frame is in the second
9 configuration;

10 a first leaflet and a second leaflet providing a bi-leaflet valve
11 configuration having a valve orifice extending in a direction between the
12 first bend and the second bend;

13 the first leaflet having a first outer edge portion attached extending
14 along a side element connected to said first bend, and a second outer
15 edge portion attached extending along a side element connected to the
16 second bend; and

17 the second leaflet having a first outer edge portion attached
18 extending along a side element connected to the first bend and a second
19 outer edge portion attached extending along a side element connected
20 to the second bend.

1 67. (New) The bi-leaflet valve of claims 66, wherein the first leaflet and